# WHAT IS XILTRIX? PROTECTING YOUR LIFE SCIENCE ASSETS 47





Building on over 30 years of experience and expertise in life science industries, XiltriX provides an autonomous, 24/7 monitoring solution that operates as a Safety Net for any life science laboratory, storage facility, or manufacturing site. All day, every day, XiltriX acts as the pulse of a laboratory's infrastructure. It checks data in real-time for any amount of sensors, assets, and equipment. It logs data securely in the cloud and generates public or personal alarms when any parameter deviates from set limits. XiltriX is designed with redundant architecture and multiple layers of safety to prevent any data loss or downtime.

Secure, cloud-based software enables users to monitor all valuable assets and equipment through an intuitive, flexible user interface. The XiltriX Saturn software instantly provides fully detailed, customized reports for auditing and diagnostics, while leveraging predictive analytics to identify potential failures before they happen. The modular, network-based design means that it can be configured to meet any current need, with ease of scalability and extensibility at any time. XiltriX is not constrained by the physical structure of the laboratory, as data transmission can be wired, wireless, or a combination of the two. Whether expanding to a new facility, integrating an existing site, or improving current monitoring processes, the XiltriX solution's flexible architecture makes it the only monitoring solution to provide users with complete role-based control over all facilities and equipment, regardless of location or brand.

The system can be fully validated and is compliant with all appropriate quality and regulatory standards: GMP, GLP, GxP, FDA 21 CFR part 11, CAP, CAPA, HACCP, JCAHO, USP 797, etc. Our subscription-based pricing includes all hardware, any necessary maintenance, repairs, and support. In addition, our Safety Net group ensures that any alerts are quickly addressed, 24/7, 365 days a year. XiltriX protects your science and helps you sleep at night.

### WHAT IS MONITORING-AS-A-SERVICE?

The XiltriX Safety Net team actively monitors and manages the XiltriX system, keeping a watchful eye on any alarms for deviations or failures, ensuring that each one is addressed appropriately. In addition to monitoring laboratory conditions and equipment operations, the XiltriX Safety Net team generates automated, custom reports for quality and compliance--which can be used during internal or external audits--and leverages predictive analytics to prevent equipment failures before they happen. The XiltriX system has multiple layers of redundancy and the XiltriX Safety Net team always ensures the system is running optimally.

Constantly evolving compliance and quality standards in life science industries such as biotechnology, pharmaceuticals, IVF/ART, cryo/ bio-banks, blood and tissue banks, etc. are becoming more stringent. In any professional laboratory, research, manufacturing, asset storage, biological processes and environmental conditions must all be critically controlled. It is very difficult for laboratory personnel to monitor all the parameters, all the time. XiltriX provides a solution that does it automatically, reliably and accurately, monitoring myriad vital parameters such as temperature, air pressure, humidity, CO2 and O2, VOCs, particles, back-up generators, and others, alerting users if any controlled parameter deviates outside set limits. XiltriX protects every detail, every sensor, every second.



The XiltriX solution instantly provides fully detailed, customized reports for auditing and diagnostics, while leveraging predictive analytics to identify potential failures before they happen.

### BENEFITS OF MONITORING

By closely monitoring all vital control parameters, XiltriX provides notifications for any equipment or ambient parameter deviations. This allows users to take preventive actions before any loss of valuable assets or catastrophic equipment failures. In addition, it will improve overall laboratory functionality, quality and compliance, and adherence to Standard Operating Procedures (SOPs). The XiltriX solution saves time and money, improves SOPs, mitigates the risk of loss, and ensures valuable samples, compounds, pharmaceuticals, eggs and embryos, blood or culture samples, or any other sensitive materials are kept under optimal conditions. The XiltriX Saturn software provides audit trails, historical data and graphical information necessary to demonstrate compliance with regulations and quality standards to auditors, customers and internal users.

# CO, AND O, MONITORING

Many life science laboratories and facilities utilize CO<sub>2</sub> incubators, or triple gas incubators, and the internal atmospheres in these types of equipment must be continuously monitored to maximize cell or culture viability. With the XiltriX system, atmosphere samples are taken from the incubator. The true concentrations of CO2 and O2, together with temperature and humidity, are measured at programmed time intervals using a system automatically calibrated against a standard gas mixture. This ensures consistency of results and prevents false alarms. XiltriX can monitor up to 16 incubators simultaneously, keeping the cost per incubator very low.

# FLEXIBILITY WITH XILTRIX

### A SOLUTION FOR EVERY NEED

Every organization, customer, laboratory and facility has unique needs. These could range from monitoring a small laboratory to monitoring large, enterprise facilities with multiple locations across different regions and thousands of sensor end-points. XiltriX is able to address the entire spectrum of needs with subscription packages sized to the scope of each specific implementation.



### SPECIFIC PARTICLE COUNTING

Particle counting is important for biotech and pharmaceutical facilities, clean rooms, and anywhere airborne particulates may pose a problem. XiltriX provides dual laser-based particle counters available for a multitude of specifications, which typically monitor particles down to 0.3µ in diameter. Two size channels are counted simultaneously and the count is transmitted digitally to XiltriX. By using digital communication there is no data loss due to signal transmission or conversion. XiltriX delivers traceable, real-time data that assures adherence to compliance efforts for GxP, as well as similar quality and regulatory protocols.

### **REAL-TIME INFORMATION ACCESS**

The XiltriX solution offers comprehensive, real-time information access through a variety of notification platforms. From computers to tablets, smartphones, emails, text messages, even pre-recorded telephone messages sent via automatic dialer. Real-time information and notifications are available on all devices and operating systems that have a web browser. The proper diagnostic information is always accessible. For example, the SMS text module provides an alarm's location and the output that triggered it. Multi-directional communication allows the user to interrogate the XiltriX system and manage the alarm situation from their computer, tablet, or mobile phone. If more information is needed than what's presented, the user can log in to XiltriX from any device with internet access to determine if additional actions are necessary.

### ALARMS AND REPORTING

When a monitored parameter deviates from pre-established limits, XiltriX alerts the user in a variety of ways. Local alarms such as sirens or flashing lights can be located centrally or near the equipment in the laboratory. Automated text messages can be sent to a designated user's mobile phone, with customized escalation protocols in the event of an absence.

The mobile phone can then be used to query the system and identify the failure. E-mail messages can be generated automatically, sent to the user's computer in the laboratory or at home, where they can view the status of the entire system. Detailed reports, statistics and historical data are available at all times. In the event of a local, or facility-wide power outage, a built-in, 48-hour battery life allows for continuous monitoring without any data loss, until power is restored.

### THE IT ENVIRONMENT-IMPLEMENTATION & CONFIGURATION

The XiltriX system never sleeps. It runs on a secure and redundant cloud-based platform, and measures the pulse of a laboratory's infrastructure continuously, in real-time. The industrial-grade hardware is built to the highest US and international standards, capable of running 24/7, for years on end with a 10+ year lifespan. XiltriX Saturn, the cloud-based software platform, uses a secure VPN connection to continuously communicate with a master substation (Calypso) and its connected sensor network, to check in real-time whether all processes, substations and sensors are online and functioning properly. XiltriX will only alert users if a serious problem needs attention, alleviating the need to routinely check the system. The user is alerted only when intervention is necessary and the system's intuitive, flexible user interface can be accessed securely from any device with an internet connection.

### CUSTOMIZABLE COMMUNICATION OPTIONS-WIRED OR WIRELESS CAPABILITIES

The XiltriX Saturn software communicates with the sensor network through hardware, Calypso modems. Calypso then communicates with sensors using either Titan, hardwired modems, or Telesto, wireless modems, each of which handles several sensor inputs. The ability to choose between wired or wireless configuration gives flexibility and scalability for the most cost-effective installation – with no difference in measuring speed between wired or wireless communication. Telestos can also be used as a wireless communication bridge between local hardwired Titan networks and Calypso modems. The 916 MHz frequency band has excellent signal penetration through walls, even in the most complicated facility floor plans. The modular design allows for complete scalability.

## XILTRIX SATURN (INDUSTRIAL GRADE SOFTWARE)

XiltriX Saturn provides an intuitive, flexible user interface, with easy implementation and configuration. The fully-virtualizable and fully-validated software enables data acquisition with scalable speeds for larger systems. The "Security by Design" architecture provides added layers of protection for an organization's valuable data. The responsive design delivers easy navigation and works on every operating system with a web browser.

Full-functionality, including the resetting of alarms and creation of graphs, enables organizations to see data how they want it, when they need it. Comprehensive and customizable user roles allow for standard, super-user and administration roles, among others. Users can be designated for one or multiple departments depending on established procedures. Management of all user roles and authorizations within each department provides cross-functional transparency throughout an organization.

The unique User Interface (UI) delivers streamlined user control across the platform. With direct resetting of alarms and alarm indications with customizable icons and animations, users are able to respond more effectively in case of any failures. This includes a standard library of icons, animations for equipment and sensors, in addition to already installed substation icons for XiltriX hardware. Simple map management with customizable map interfaces and substation configuration for user based roles enables the right user, to monitor the right area, at the right time. Allowing for total control over every detail, every sensor, every second.



### SUBSCRIPTION PRICING WITHOUT SUBSTANTIAL CAPITAL INVESTMENT

The XiltriX solution is offered as a subscription model which means there is no large upfront capital investment, and customers benefit from the use of hardware and the latest version of software throughout the subscription term, without any additional maintenance, repair or upgrade costs.

During the subscription term, the XiltriX support team will perform any hardware repairs or replacements, and any software or security updates at no additional cost. The subscription model also includes remote monitoring from the Safety Net team and any additional customer support.

# **EQUIPMENT**

# XILTRIX EQUIPMENT FOR EVERY MONITORING NEED

### Sensors:

- Temperature: a range of Class A Pt100 sensors covering temperatures down to -200°C and up to +250°C. Different models for culture vessels, incubators, refrigerators, freezers, and surfaces (such as microscope platens)
- CO<sub>2</sub> and O<sub>3</sub>: vital for IVF and other applications of CO<sub>2</sub> and triple gas incubators. Single sensors or unique, 16-channel CO<sub>3</sub>, and O<sub>2</sub> substations with automatic sampling and calibration.
- Pressure: differential pressure transmitters to monitor ambient pressure in laboratories, clean rooms, etc.
- Humidity: measure relative humidity in CO<sub>2</sub> incubators, refrigerators, or clean rooms.
- Particles: particle counters for biosafety and clean room areas
- Door sensors: in the event an incubator or refrigerator is left open
- Conductivity: measure water purity
- Shaking: monitor thrombocyte shakers, etc.
- Special sensors available upon request

### **Data Transmitters:**

The building blocks of the XiltriX system. Compatible with a wide range of sensors and adaptable to evolving sensor technology. Compact units that have a modular design for ease of scaling in wired or wireless connection options between sensors and the central server. All with a 10+ year lifespan and built-in, 48-hr battery power for redundancy in case of power failure:

- Calypso: multifunctional communications between the sensor network and the system server via wireless (916 MHz) or wired (RS485) connections
- Titan: wired (RS485) communications interface between sensors and Calypso
- **Telesto**: wireless (916 MHz) or wired (RS485) communications between the sensor network and Calypso

### **Software**

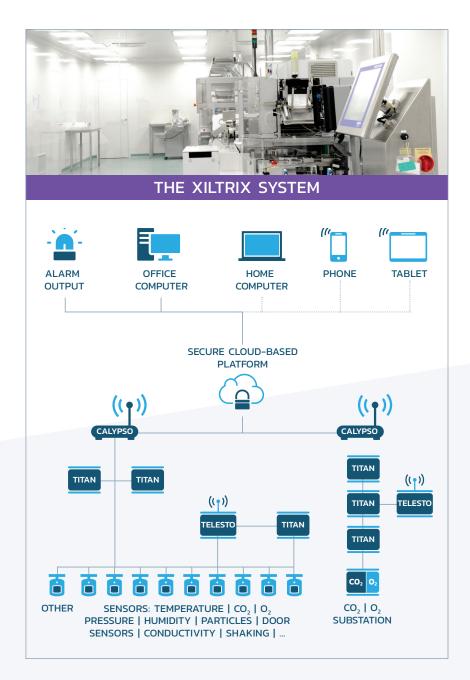
Cloud-based, the XiltriX Saturn solution, menudriven software with full reporting that includes:

- Historical reports generated in seconds
- Graphs, numerical values and statistical information from any sensor at any time
- Up to 8 parameters displayed simultaneously for easy comparison and trend analysis
- Exports of all numerical and statistical data to MS Excel<sup>™</sup> compatible files
- Statistics including all commonly used values i.e. MKT (Mean Kinetic Temperature)

### **Alarm Options**

Whether users are in the lab, or at home, there is immediate notification of equipment failure or imminent breakdown:

- Warning lights or sirens for on-site alarms
- Text message notifications, with accurate event description and receipt acknowledgment
- E-mail alerts including accurate event description
- Mobile or telephone dialer with pre-recorded messages



# **VALIDATION**

### A Fully-Validatable, Auditable Solution

Many XiltriX installations are in laboratories operating in heavily regulated environments, where system validation is an essential part of the implementation. To meet the highest quality standards, on request, XiltriX can provide the functional specification documentation to ensure validation is in the right place. The system can be fully validated and is compliant with all appropriate quality and regulatory standards: GMP, GLP, GxP, FDA 21 CFR part 11, CLIA, CAP, CAPA, HACCP, JCAHO, USP 797, etc.

# MANAGED MONITORING SERVICES

### The XiltriX Safety Net

Through its seamlessly integrated hardware and secure, cloud-based software solution, XiltriX provides increased oversight with 24/7 monitoring by the XiltriX Safety Net team, which alleviates the burden of managing the system.

Identifying and implementing an effective laboratory monitoring system can be a complex process that impacts many functions and disciplines within an organization. Every environment can be unique and has to be evaluated, not just for the technical requirements of laboratory staff but also for the needs of other stakeholders such as an IT or procurement department. Facility floor plans and the layout of equipment in laboratory buildings almost always have implications for the design and installation of any system. The XiltriX team has an in-depth appreciation for the needs, priorities, and risks involved in this process and will work with customers to design the best solution for any environment. The aim is to not only offer an intuitive and flexible solution with fail-safe, purpose-built equipment and active monitoring, but also to provide proper guidance and advice necessary to implement a comprehensive, cost-effective solution.

XiltriX guides customers through the entire evaluation process, from defining priority needs to segmenting the complex steps of decision making into a clear roadmap that produces practical, measurable results. This ensures the solution fully satisfies an organization's needs and makes certain that the XiltriX monitoring solution integrates seamlessly into the laboratory and quality environments. This can include system integration with other suppliers' equipment.

XiltriX has trained implementation specialists and support staff as essential partners in the operation of the laboratory monitoring system. In addition to comprehensive, on-site training and support, the XiltriX Safety Net staff will assist customers in identifying any system parameter deviations and addressing critical alarms. XiltriX protects your science and helps you sleep at night.

	XILTRIX	OTHERS
Architecture	Cloud-based, with a central management, web and mobile GUI interface.	Frequently logging-based (contains fragmented architecture). Limited configurability, usually not centrally managed.
Security	Utilizes the latest software and data security protocols, role-based access levels, and central management systems.	Many others use premise-based software that is often outdated and not user-friendly.
Redundancy	Multiple levels of redundancy in power, connectivity, and alarm escalation protocols.	Due to limited nature, single points of failure are extremely common.
Scalability	Unlimited, with modular architecture. Easily set up and add new end-points or locations.	Contain limited to very few hundred end-points.
Measurement Frequency	Real-time, minimum of every minute, pinging every second in an event of an alarm.	Updates occur every 15 to 60 minutes. No-real time data.
Alarm Timelines	Immediate alarm system with cascading escalation protocols that include e-mail, SMS, and phone. Alarms are monitored at all times to ensure timely response.	Loggers push data to transceiver periodically. If network is congested, there is a risk of alarm signals not being properly received or even dropped.